nephron pharmaceuticals corporation

Date: 02-01-2017

# SAFETY DATA SHEET

## SECTION 1: IDENTIFICATION

**Nephron Pharmaceuticals Corporation**
4500 12th Street Extension
West Columbia, SC 29172-3025
(803) 569-2800
(800) 443-4313 (24 hour contact)

PRODUCT NAME: Budesonide Inhalation Solution 0.25mg/2mL & 0.5 mg/2mL
COMMON NAME: Budesonide
CHEMICAL NAME: 16, 17-Butylidenebis(oxy)-11,21-dihydroxypregna-1,4-diene-3,20-dione
INN:
SUBSTANCE CLASS:
INTENDED USE: Pharmaceutical Use for Inhalation

## SECTION 2: HAZARD(S) IDENTIFICATION

Carcinogenicity: (NTP) No (IARC) No (OSHA) No
Eye: No known significant effects or critical hazards, may cause irritation.
Skin: No known significant effects or critical hazards, may cause irritation.
Ingestion: No known significant effects or critical hazards.
Inhalation: No known significant effects or critical hazards, may cause respiratory irritation.
Chronic Effects: No known significant effects or critical hazards.
Target Organs: No known significant effects or critical hazards.
Medical Conditions Aggravated by long Exposure: No known significant effects or critical hazards.
(See Section 11, "Toxicological Information")

## SECTION 3: COMPOSITON / INFORMATION ON INGREDIENTS

| | |
|---|---|
| NAME: | Budesonide |
| CAS#: | 51333-22-3 |
| % w/v | 0.25mg/2mL & 0.5mg/2mL |
| GW Limits | Not Established |
| Other Limits: | Not Established |
| Name: | Water for Injection |
| CAS# | 7732-18-5 |
| % w/v | 0.25mg/2mL 99.02 %w/v & 0.5mg/2mL 99.01 %w/v |
| Name | |
| CAS# | |

## SECTION 4: FIRST AID MEASURES

If In Eyes: Flush with large amounts of cool water for at least 15 minutes. Obtain medical attention.

If On Skin: Wash affected areas with soap and water after removing contaminated clothing. Obtain medical attention if contamination is significant and/or a skin reaction is evident.

If Inhaled: If not breathing, give artificial respiration or CPR. If breathing is difficult, give oxygen. Obtain medical attention and remove to fresh air.

If Ingested: Flush mouth out with water, drink several glasses of water. Never give anything by mouth or induce vomiting if unconscious or having convulsions. Obtain medical attention.

## SECTION 5: FIRE FIGHTING MEASURES

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|---|---|
| FLASH POINT/TEST METHOD: | Unknown. |
| LEL/UEL: | Unknown. |
| SPECIAL PROPERTIES RELATED TO FIRE HAZARD: | Carbon Oxides |
| STORAGE OR HANDLING CONDITIONS TO BE AVOIDED: | Extreme Heat. |
| EXTINGUISHING MEDIA: | Water Spray, Alcohol-Resistant Foam, Dry Chemical, or Carbon Dioxide |
| FIRE-FIGHTING PROCEDURES: | Wear full protective clothing and use self-contained breathing apparatus (SCBA). Use water spray to keep fire exposed containers cool. |

## SECTION 6: ACCIDENTAL RELEASE MEASURES

SPILL RESPONSE PROCEDURES (Liquid, Solid, Gas/Vapor):

Protective equipment may be necessary for spills, (See Section 8, “Exposure Controls / Personal Protection” for guidance).

Use personal protective equipment. Contain the spill to prevent drainage into sewers,drains or streams. Use absorbent materials to solidify the spill. Shovel or scoop up solidified waste. Dispose of material according to Federal, State and Local regulations.

## SECTION 7: HANDLING AND STORAGE

HANDLING: Avoid Contact with eyes. Pregnant women shall avoid exposure to this product.

STORAGE: Protect from sunlight, Store between 20° -25C° (68° -77° F). Store in an upright position.

## SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

ENGINEERING CONTROLS: In manufacturing plant, provide adequate ventilation for the raw material handling and compounding process which will maintain the dust and vapor levels below the TLV, STEL, and PEL values for the ingredients. Ventilation fans should be explosion proof. Use adequate personal protective equipment e.g. NIOSH-approved respirators, goggles or safety glasses, gloves and protective clothing. Ensure training in the handling of chemical material and use current Safety Data Sheets.

PERSONAL PROTECTION:

Respiratory: Not required under normal conditions of therapeutic use. See Section 5 “ Fire-Fighting Measures” for respiratory protection in the event of a fire. Where protection from nuisance levels of dusts are desired use type N85 (US) or type P1 (EN 143) dust masks.

Eye: Not required for recommended dosage and administration. Workers should wear goggles or adequate eye protection if splash hazard exists.

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| Clothing: | Adequate protective clothing should be worn to prevent occupational skin contact. |
| Gloves: | When routine handling or spill cleanup may result in skin contact, impermeable (e.g., latex) gloves should be worn. Where protection from nuisance levels of dusts are desired use type N85 (US) or type P1 (EN 143) dust masks. |
| Work Practices: | Special care should be taken to ensure that contaminated clothing, equipment and work surfaces are properly cleaned after use. Wash hands and other areas of skin contact thoroughly with soap and water. Release rinse water into an approved wastewater system according to Federal,State and Local regulations.<br>handling this material. Contaminated clothing should be cleaned or disposed of. |

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

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| APPEARANCE AND ODOR: | Clear, colorless solution with little or no odor. |
| PHYSICAL STATE: | Liquid Solution |
| MELTING POINT: | Not determined. |
| BOILING POINT: | Not determined. |
| SOLUBILITY/MISCIBILITY (%w/v): | Not determined. Water soluble |

## SECTION 10: STABILITY AND REACTIVITY

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|---|---|
| CHEMICAL STABILITY: | Stable. |
| CONDITIONS TO AVOID: | None known. |
| INCOMPATIBILITY WITH OTHER MATERIALS: | Strong oxidizing agents |
| HAZARDOUS DECOMPOSITION PRODUCTS: | In the event of fire refer to Section 5 |

## SECTION 11: TOXICOLOGICAL INFORMATION

**Toxicological information refers to raw materials product. Concentrations and toxicological effects are substantially reduced in the product. For more detailed information see the SDS on raw chemical material.**

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|---|---|
| ENVIRONMENTAL FATE: | Not known |
| ENVIRONMENTAL EFFECTS: | Not known |
| ENVIRONMENTAL TEST RESULTS: | N/A |

## SECTION 13: DISPOSAL CONSIDERATIONS

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|---|---|
| ROUTINE | Unused product should be disposed of at an approved facility in accordance with federal, state and local regulations. |
| ACCIDENTAL RELEASE: | Clean up spills immediately, observing precautions in Section 8 - “Exposure Controls / Personal Protection”.<br>Remove or decontaminate all residues in accordance with federal, state and local regulations. |

## SECTION 14: TRANSPORT INFORMATION

Component 1 or Formulation 1: Budesonide Inhalation Solution 0.25mg/2mL & 0.5mg/2mL

**US Department of Transportation**
Proper Shipping Name: Not Regulated

**IATA/ICAO**
Proper Shipping Name: Not Regulated

**IMDG**
Proper Shipping Name: Not Regulated

RQ: None Marine Pollutant: No

## SECTION 15: REGULATORY INFORMATION

EC PACKAGING AND LABELING FOR SUPPLY: Not applicable.

OTHER LEGISLATION: Not regulated.

## SECTION 16: OTHER INFORMATION

DATE: 04-21-2015

TO THE BEST OF OUR KNOWLEDGE THE INFORMATION CONTAINED HEREIN IS ACCURATE AS OF THE DATE HEREOF. ANY DETERMINATION AS TO THE SUITABILITY OF THE PRODUCT FOR ANY PARTICULAR PURPOSE, ITS SAFE USE OR DISPOSAL, SHALL BE THE RESPONSIBILITY OF THE USER. THE INFORMATION CONTAINED HEREIN IS IN NO WAY INTENDED TO SUPPLEMENT, MODIFY, OR SUPERSEDE THE INFORMATION PROVIDED IN THE PRODUCT PACKAGE INSERT WITH RESPECT TO THE USE OF THE PRODUCT FOR MEDICAL PURPOSES. PLEASE REFER TO THE PRODUCT PACKAGE INSERT FOR INFORMATION REGARDING THE USE OF THE PRODUCT FOR MEDICAL PURPOSES.